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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/523,237	03/10/00	BECKER M	GP068-03.CN1

021365
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HM12/0118

EXAMINER	
SHIBUYA,M	
ART UNIT	**PAPER NUMBER**
1635	7

DATE MAILED: 01/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

U.S. G.P.O. 1999-460-999

Office Action Summary	Application No.	Applicant(s)	
	09/523,237	BECKER ET AL.	
	Examiner	Art Unit	
	Mark Shibuya	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *422-441* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *422-441* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 & 5* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Specification

1. In the Brief Description of the Drawings at p. 10, "Figure 1" in line 14, should be referred to as --Figures 1A-C--.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 422-441 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 444-465 of copending Application No. 09/565,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because the kits for amplifying a target nucleic acid sequence contained in a target nucleic acid, said kit comprising an oligonucleotide primer containing a first base region which forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety of the

instant application *encompass* the kits for determining the presence of a target organism or group of organisms that comprises an oligonucleotide probe containing a first base region which forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety, and because primers and probes can be interchangeable.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 422, 427-431, 433-441 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Gemen et al., Patent No. 5,679,553.

a. Van Gemen et al., Patent No. 5,679,553, at col. 2, lines 42-47, 55-56, col. 4, lines 28-34, 45-61, col. 5, lines 6-11, col. 5, lines 28-67, col. 6, lines 1-15, col. 7, line 19-67, col. 8, line 1-25, col. 10, 49-67, disclose kits for amplifying a target nucleic acid sequence contained in a target nucleic acid, said kit comprising an oligonucleotide primer containing a first base region which

forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety; and that would inherently have written instructions for use of said kits.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 423-426 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gemen et al., Patent No. 5,679,553.

a. Van Gemen et al., Patent No. 5,679,553, at col. 2, lines 42-47, 55-56, col. 4, lines 28-34, 45-61, col. 5, lines 6-11, col. 5, lines 28-67, col. 6, lines 1-15, col. 7, line 19-67, col. 8, line 1-25, and especially at col. 10, 49-67 and col. 7, lines 34-40, disclose kits for amplifying a target nucleic acid sequence contained in a target nucleic acid, said kits comprising an oligonucleotide primer containing a first base region which forms a stable hybrid with a second base region

contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety; and that would inherently have written instructions for use of said kits.

b. Van Gemen et al. does not teach first base regions that would include at least 4, 6, 8 or all ribonucleotides that are of said modified ribonucleotides.

c. It would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to have made and used kits comprising an oligonucleotide primer containing a first base region which forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety, wherein said first base regions that would include at least 4, 6, 8 or all ribonucleotides that are of said modified ribonucleotides. One of ordinary skill in the art would have been motivated to make and use oligonucleotide primers wherein said first base regions that would include at least 4, 6, 8 or all ribonucleotides that are of said modified ribonucleotides in a routine course of optimization.

8. Claim 432 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gemen et al., Patent No. 5,679,553 in view of Cruickshank, Patent No. 5091519.

a. Van Gemen et al., Patent No. 5,679,553, at col. 2, lines 42-47, 55-56, col. 4, lines 28-34, 45-61, col. 5, lines 6-11, col. 5, lines 28-67, col. 6, lines 1-15, col. 7, line 19-67, col. 8, line 1-

25, and especially at col. 10, 49-67 and col. 7, lines 34-40, disclose kits for amplifying a target nucleic acid sequence contained in a target nucleic acid, said kits comprising an oligonucleotide primer containing a first base region which forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said first base region contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety; and that would inherently have written instructions for use of said kits.

b. Van Gemen et al. does not teach acridinium ester as a chemiluminescent probe label.

c. Cruickshank, Patent No. 5091519, at col. 9, lines 45-48, col. 13, lines 21-24, disclose using acridinium ester as chemiluminescent labels to detect nucleic acid hybridization.

d. It would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to have made and used kits comprising an oligonucleotide primer containing an acridinium ester as a chemiluminescent probe label. One of ordinary skill in the art would have been motivated to make and use oligonucleotide primers comprising acridinium ester as chemiluminescent labels in order to detect nucleic acid hybridization, as taught by Cruickshank.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC),* whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

11. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technical Center 1600
January 3, 2001

ANDREW WANG
PATENT EXAMINER
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